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General Comment

Please accept the attached comments on behalf of EnergySolutions.

Thank you,

Dan Shrum

Attachments

CD15-0207 09-14-2015 Cover Letter for Hormesis vs LNT

September 14, 2015 CD15-0207

Secretary
U.S. Nuclear Regulatory Commission,
Washington, DC 20555–0001

ATTN: Rulemakings and Adjudications Staff

Reference: **NUCLEAR REGULATORY COMMISSION 10 CFR Part 20, [Docket Nos. PRM–20–28, PRM–20–29, and PRM–20–30; NRC–2015–0057] Docket ID NRC–2011–0012 and Docket ID NRC-2015-0003; *Federal Register* 35870 Vol. 80, No. 120, Tuesday, June 23, 2015**

Action: **Petition for rulemaking; notice of docketing and request for comment**.

Subject: **Comments to Linear No-Threshold Model and Standards for Protection Against Radiation**

Dear Secretary:

Energy*Solutions* appreciates the opportunity to provide comments in response to the *Federal Register* notices regarding the U.S. Nuclear Regulatory Commission's (NRC) Petition for rulemaking under 10 CFR Part 20 concerning the Linear No-Threshold (LNT) Model and Standards for Protection Against Radiation. The proposed rulemaking is of interest to Energy*Solutions* as we believe it presents an opportunity to redefine the effects that radiation has on human health and to update standards for radiation exposure based on contemporary science and decades of actual industry data. Moreover, it also presents industry with an opportunity to redefine its best practices for controlling exposure to radiation in a way that is more commensurate with the hazard. It is noteworthy that France, Japan and China have already accepted the Hormesis Theory over the LNT Model indicating that changes within the international community to bring radiation protection standards in line with 75 years of knowledge are gaining momentum.

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The LNT Model was first adopted by the Genetics Panel of the National Academy of Sciences (NAS) Biological Effects of Atomic Radiation (BEAR) I Committee in 1956. Since then, the model has been used to derive radiation exposure limits for workers and the members of the general public and further formed the foundation for the radiation protection principle of keeping exposures As Low As Reasonably Achievable (ALARA). Notwithstanding the absence of reliable evidence that low levels of exposure cause harmful health effects and increased risk of cancer, radiation exposure limits have been consistently lowered over the years because of this principle of linearity.

Our comments on the docket and the merits of using the Hormesis Theory assumes a threshold for radiation exposure consistent with contemporary science and occupational worker studies which indicate lower incidences of cancer, including leukemia, lends credibility to the Hormesis Theory. Whereas the LNT Model assumes, exposure to radiation at any level, has harmful health effects.

The adoption of a threshold, below which harmful effects do not occur, would have a positive impact on several aspects of our nuclear facility operations, including worker training, protective equipment usage and maintenance, radiation monitoring, documentation and recordkeeping. Not only would resources be optimized and costs reduced, but there would be a positive impact on the inevitable tradeoff between required worker protection to reduce exposure to radiation and the negative impact of the associated protective equipment on impaired vision and mobility, often resulting in unnecessary industrial accidents.

At Energy*Solutions,* should these new limits be adopted, we would modify our implementation of the ALARA principle to recognize that exposures below the newly established threshold require no additional reductions. Those changes would generate resource savings and operational efficiencies by no longer subscribing to concepts that provide no tangible protection to the worker. Furthermore, consistent with the proposed 10 CFR Part 61 rulemaking, the allowable annual radiation exposure to an inadvertent intruder from a low level radioactive waste disposal site, including our site in Clive, Utah, would be kept ALARA during the performance period of 10,000+ years. The courts have ruled that ALARA is the radiation standard published in 10 CFR 20 thereby resulting in an annual exposure standard of 500 mrem/yr (5 mSv/yr) or if changed, a maximum of 5,000 mrem/yr (50mSv/yr) for the performance period.

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One final consideration is the likelihood of reducing insurance premiums funded by the nuclear industry to satisfy requirements from the Price-Anderson Nuclear Industries Indemnity Act. Operating commercial nuclear facilities must fund this insurance to offset any potential liability claims that could arise in the event of a nuclear incident. Given the Fund's solvency and an objective redefinition of radiation exposure limits, should an incident occur, the basis for adjudicating resultant claims is vastly different. This would tend to ensure the Fund's longer-term integrity and should reduce the industry's cost to maintain this liability insurance.

This letter serves to lend our support for shifting from the LNT Model to the Hormesis Theory as the basis for establishing threshold limits for radiation exposure and to significantly lessen ALARA as a requirement in controlling radiation exposure. Our comments are contained in the attached enclosure which delineates specific comments, supporting data and recommendations for your consideration.

Thank you again for this opportunity to comment. Questions regarding these comments may be directed to me at (801) 649-2109 or dshrum@energysolutions.com.

Sincerely,

Daniel B. Shrum
Senior Vice President, Regulatory Affairs

ENERGY*SOLUTIONS* COMMENTS ON PETITIONS FOR RULEMAKING REGARDING THE LINEAR NO-THRESHOLD MODEL AND STANDARDS FOR PROTECTION AGAINST RADIATION

As described in our cover letter, Energy*Solutions* supports the petitions for rulemaking in favor of promulgating more realistic regulations for the protection of workers and the general public from the potential adverse effects of radiation. Specific points that provide the basis for our position are given below.

1. Current relevant science and research challenge the accuracy of the Linear, No-Threshold (LNT) model of radiation carcinogenesis.

The LNT model was first adopted by the Genetics Panel of the National Academy of Sciences (NAS) Biological Effects of Atomic Radiation (BEAR) I Committee in 1956. The principle is that all levels of radiation dose (e.g., millirem or mrem or millisievert or mSv) carry some non-zero risk of inducing or promoting cancer, including the natural background radiation dose.[1] This model has been used to derive radiation dose limits for workers, the general public, pregnant workers, and others, and is the foundation for the radiation protection principle of keeping doses "As Low As Reasonably Achievable" (ALARA). The most recent proclamation of the NAS Biological Effects of Ionizing Radiation (BEIR) VII was that "The committee judges that the balance of evidence from epidemiologic, animal and mechanistic studies tends to favor a simple proportionate relationship at low doses between radiation dose and cancer risk." This was after an extensive review of the scientific literature. Interestingly, however, at the same time, studying the same body of data, the French Academy of Sciences concluded that

> …this report raises doubts on the validity of using LNT for evaluating the carcinogenic risk of low doses (<10,000 mrem [< 100 mSv]) and even more for very low doses (<1,000 mrem [< 10 mSv]). The LNT concept can be a useful pragmatic tool for assessing rules in radioprotection for doses above 1,000 mrem (10 mSv); however since it is not based on biological concepts of our current knowledge, it should not be used without precaution for assessing by extrapolation the risks associated with low and even more so, with very low doses…

Radiation dose limits have been consistently lowered over the years because of this principle of linearity. The principle source of data used as the basis for the study of radiation carcinogenesis are the survivors of the Japanese bombings, the so-called "life span study" (LSS) cohort, although many other cohorts exist (e.g., persons medically irradiated in the early 1900's). Overall, there is no reliable evidence of radiation causing cancer below 10,000 mrem (100 mSv),

[1]Natural background dose can range from around 50 to 150 mrem/yr (0.5 to 1.5 mSv) or greater depending on what part of the country an individual lives for all individuals.

yet radiation worker limits are 5,000 mrem/yr (50 mSv/year) (with discussion to lower them to 2,000 mrem/yr (20 mSv/year)), the limit for the general public is 100 mrem/yr (1 mSv/year), and the dose limit for the fetus of a declared pregnant woman is 500 mrem/yr (5 mSv) during gestation 10 CFR 20, NRC, 2015). The idea of using a simple, linear model down to zero dose is appealing in its simplicity and clarity.

At the time that BEIR VII was written, evidence had been published suggesting that low doses of radiation might not be harmful to people, but might in fact be *beneficial*, a theory sometimes called "hormesis". The idea is that low doses of radiation may stimulate immune responses that actually reduce the likelihood of cancer induction; this is called 'adaptive response'. Proponents of hormesis were disappointed by the BEIR VII Committee's rejection of the idea with a short 4 page treatment of the data in an appendix. Doss (2013) provides a summary of the case for LNT:

- Ten controlled in-vitro and animal studies that show adaptive response to low dose radiation.
- Evidence that Excess Relative Risk (ERR) data from the LSS cohort is not linear at low doses, and shows a possible threshold or even hormetic shape.
- Demonstration of lower than average cancer rates in a population of residents who lived in buildings in Taiwan that were unknowingly constructed with Co-60, giving a continuous low level dose over years.
- Lower incidence of cancer from low doses received by some tissues during radiation therapy.

Two of the petitioners to the NRC further note:

- 400,000 nuclear power industry workers from 154 facilities in 15 countries had lower than average rates of all cancers, including leukemia.
- Patients with tuberculosis in Canada were subjected to multiple fluoroscopies receiving doses 50-300 mSv had 1/3 less breast cancer incidence than background.
- Bone sarcomas and carcinomas in the radium dial watch painters had a clear threshold of 10,000 mGy.
- Lower than expected cancer rates in a population receiving radiation doses to 500 mSv due to release of radioactive waste from a nuclear fuel reprocessing facility in Russia.

Due to fears related to low dose radiation in the Fukushima incident, thousands of people were evacuated from a contaminated area, and 1,600 accidental deaths occurred. The residents remain fearful of returning to their homes still and around 160,000 have been evacuated due to fear of radiation (Fukushima on the Globe. July 14, 2015). The constant chanting of the mantra that there is 'no safe dose of radiation,' or worse yet, proclaiming that thousands of cancer deaths

are being caused by medical studies using radiation (Brenner and Hall, 2008; Brenner et al., 2007) are causing people to refuse needed medical studies for themselves or their children. In the workplace, the nuclear power and other industries expend immense efforts and spend billions of dollars protecting workers and the public from dose levels that are not known to be harmful, and in fact may be beneficial. This effort and money could be better spent on addressing other safety concerns that actually reduce morbidity and mortality.

2. Adoption of a higher occupational dose standard of 10 rems per year (1,000 millisieverts per year [mSv/yr]) in lieu of ALARA could result in operational efficiencies, improvements in worker safety, and reduction of regulatory and monitoring burdens with no reduction in human health and safety.

There is a long history of attempts by the NRC to adopt regulatory measures that are consistent with a threshold below which the Commission would not take action, beginning with "As Low As Practicable (ALAP)" in the late 1960's through the early 1970s.

In July of 1975 the Commission proposed to replace ALAP with "As Low As Reasonably Achievable" (ALARA), taking into account technology capability and cost-benefit considerations. (Permissible Dose, 2000)

However, the ALARA concept can be misused and used to justify costly expenditures and practices that do not contribute to safety. Quite simply, if one has reached an acceptable safe level, below which there is no harmful exposure (threshold) there is no basis to continue to commit resources to further reduce potential exposures. The only justification is the adoption of a linear no-threshold model (LNT).

The current radiation protection standards given in 10 CFR 20 incorporate significant safety factors. Dr. Eric Loewen, a past president of the American Nuclear Society (ANS), in an address to the Eastern Washington and Trinity Sections of the ANS, put forth two reasons why regulatory ALARA "guidance' for Federal (DOE and DOD) facilities and commercial businesses add real costs for nuclear sciences and technologies without any added benefits (Loewen, May 19 and 20, 2011). In his written address he states that

> It takes an acute dose of 50,000 mrem to produce detectable changes in human blood. The probability of such a dose accumulation approaches zero during routine operations and maintenance in our well-established industry. Is tracking 2 to 10 mrem on a routine job worth the effort?

The maximum allowed radiation exposure per year for a radiation worker has a factor of safety of 10 times the known effects level and the allowable radiation exposure for the workers as a group is 1,000 mrem/yr or 10 mSv, which has a factor of safety of 50. Even background

radiation levels to all individuals can fluctuate by as much as several hundred mrem per individual depending on such things as location, altitude, air travel, and medical procedures. Medical procedures alone can bring an individual within the general population to over the 1,000 mrem/yr (10 mSv) for the average nuclear worker (CT scan equivalent to 2,000 mrem (20 mSv) (http://www.ans.org/pi/resources/dosechart/)). Therefore, background and anthropogenic sources (including medical procedures) can result in annual radiation exposures to individuals of 600 to 3,000 mrem (6 to 30 mSv) versus the recommended general population radiation dose levels of 100 to 500 mrem/yr (1 to 5 mSv/yr).

Dr. Loewen went on to point out that he does not accept the LNT model that assumes that there is no safe level of radiation and stated that "Radiation hormesis proponents would point out that real human data disproves our current LNT regulations."

The courts have also ruled on ALARA. Wiedus and Jose (1996) reported on two cases, one involving a lawsuit initiated by a single worker at the San Onofre Nuclear Power Plant and the other one from approximately 2,000 plaintiffs around Three Mile Island that was initiated following the incident there. In both cases there were no exposures over either the radiation worker limits or the general public radiation limits. Rather, ALARA was used as a Standard of Care and the jury was tasked to determine that standard in order to satisfy ALARA. In the end, the jury (San Onofre case where the worker had 31 mrem total exposure for the period from 1982 through 1986) ruled that the Standard of Care was defined as the federal radiation standards and for the TMI case, the jury concluded that standard was violated. The TMI case was appealed to the 3rd District of the U.S. Court of Appeals and the Appeals Court ruled that ALARA was not violated since radiation standards for individuals of the population were not violated (2,000 plaintiffs all less than the 100 mrem per year federal standard for the general population). In both of the cases, there was no acceptance of ALARA outside of a general guideline of practice. The regulatory limits were the final decision of the court and thus the standard of care or ALARA was met if the radiation dose limits were met.

The NRC proffered the concept of a threshold in its suggested approach to "Below Regulatory Concern" (BRC). They suggested 1 mrem (0.01 mSv) initially, but later revised this to 10 mrem (0.1 mSv). The USEPA had considered 4 mrem (0.4 mSv) and the NRC Advisory Committee on Reactor Safeguards suggested 3 to 5 mrem (0.03 to 0.05 mSv). Note that all of these suggested BRC levels were made within the context of the LNT model and incorporate the assumption that there is no threshold (Permissible Dose, 2000).

The Commission later issued a moratorium on BRC policy statements and, in the face of extreme opposition; they withdrew the BRC proposal on August 18, 1993 (Permissible Dose, 2000).

So, while there have been prior failed attempts by the NRC to set a "threshold," the scientific community has since accumulated substantial evidence for a threshold, below which exposures to radiation are not harmful but may, in fact, be beneficial (see Section 1 of this document).

The manpower to meet the ALARA requirements can be substantial and costs can be excessive. For example, Dr. Loewen cited statistics from the Department of Energy (DOE) Pantex Plant where 60 employees are dedicated to ALARA operations or monitoring other ALARA staff operators for primarily alpha radiation and for the 104[2] nuclear power plants where around 350 professionals are devoted to ALARA regulatory compliance. These impacts are especially noteworthy if in fact there is no added benefit to the health of the worker or a potentially exposed population and it may be counterproductive as suggested by the hormesis theory.

If the NRC regulations are modified to incorporate the impact of the hormesis theory, such that the existence of a threshold is included in the dose/ risk model, Energy*Solutions* could modify their radiation protection programs and reallocate resources, thereby providing improved efficiencies for its different business functions in the radioactive material field without materially affecting the health of the workers. The magnitude of these efficiencies depends on the magnitude of the regulatory changes. Currently, the premise of radiation protection regulations (i.e. 10 CFR 20) is that "more radiation dose equals more stochastic (random probability) risk" or the reverse. This premise is the impetus for the ALARA philosophy, which essentially drives a radiation protection program to evaluate the sources of radiation (i.e. isotope and activity) and remove or reduce its interaction (pathways) to a member of the public or a radiation worker (i.e. inhalation, ingestion or direct radiation) through time, distance or shielding. Subsequently, a change in the radiation risk model, as proposed, would modify the ALARA concept to recognize that doses below the threshold do not need to be reduced and this change would reduce the time and resources needed for regulatory compliance of a concept that provides no real protection to the worker. Also incorporation of the hormesis implications would have a positive impact on radiation risk communication in that the public could be told that there are in fact safe exposure levels below which harm does not result from exposures. As mentioned previously, the courts have ruled that ALARA serves no practical purpose since the NRC has provided limits that are protective (10 CFR 20).

The adoption of a threshold, below which harmful effects do not occur, would have an enormous impact on several aspects of nuclear facility operations, including worker training, protective equipment usage and maintenance, radiation monitoring, documentation and recordkeeping. Not only would resources be optimized and costs reduced, but there would be a net positive impact on the inevitable tradeoff between required worker protection to reduce exposure to radiation and the negative impact of the associated protective equipment on impaired

[2] Since reduced to 100.

vision and mobility, resulting in unnecessary industrial accidents. These are real deaths and not hypothetical LNT deaths that cannot be measured.

3. Impacts to the newly proposed changes to 10 CFR 61 as it relates to the inadvertent intruder scenario link to the proposed changes to an individual and/or to individuals of the general population

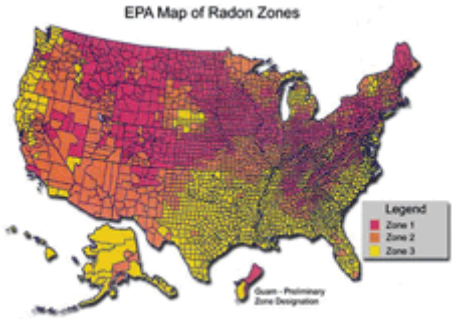
Consistent with the proposed 10 CFR Part 61 rulemaking, the allowable annual radiation dose to an inadvertent intruder from a low level radioactive waste disposal site, including the Energy*Solutions* site in Clive, Utah, would not exceed 500 mrem/yr (5 mSv/yr) for the compliance or protective assurance periods. During the performance period of 10,000+ years, the radiation doses would be ALARA. The courts have ruled that ALARA is the radiation standard published in 10 CFR 20 thereby resulting in an annual dose standard of 500 mrem/yr (5 mSv/yr) or if changed, a maximum of 5,000 mrem/yr (50mSv/yr) for the performance period.

The U.S. EPA standard for action to alleviate indoor radon concentrations is 4 picocuries per liter (pCi/L) which is equal to a radiation dose of 162 mrem/yr (1.6 mSv). Although the U. S. EPA says this level will prevent 21,000 cancer deaths per year, all U.S. EPA data are based on the "Precautionary Principle" and not "Causation," which the U.S. Court System is based. That is, there are no cancer statistics to support this claim of LNT or that cancers occur down to a near-zero level of radiation exposure. The indoor radon levels vary across the U.S. and can vary from less than 100 mrem/yr (1 mSv/yr) to over 3,000 mrem/yr (30 mSv/yr) in indoor air, as shown in Figure 1. The incidences of lung cancer by state (CDC 2014) are presented in Figure 2. As presented in the below figures, states with the lowest incidences of lung cancer often have radon levels that are some of the highest in the U.S. It is further noted that, states like Kentucky also have high radon levels, but they also have some of the highest number of people who smoke cigarettes in the nation.

The maximum dose rate for an inadvertent intruder after the site is closed is 500 mrem/year or 5 mSv/yr. The areas in orange and red shown below in Figure 1 can exceed 500 mrem/yr from natural sources. So the inadvertent intruder is already exposed to higher radiation levels than the 10 CFR 20 limits. The lung cancer rates do not support that these higher naturally occurring radiation levels result in increased cancer regardless of the U. S. EPA's claims of 21,000 additional cancer deaths from radon. They do support the exact opposite that "hormesis" or a threshold for radiation does exist and that people have adapted to these background radiation doses for the better.

The USEPA (http://www.epa.gov/radon/zonemap.html) has published a map of radon levels in the U.S. as presented in Figure 1.

Figure 1. Radon levels in the U.S.

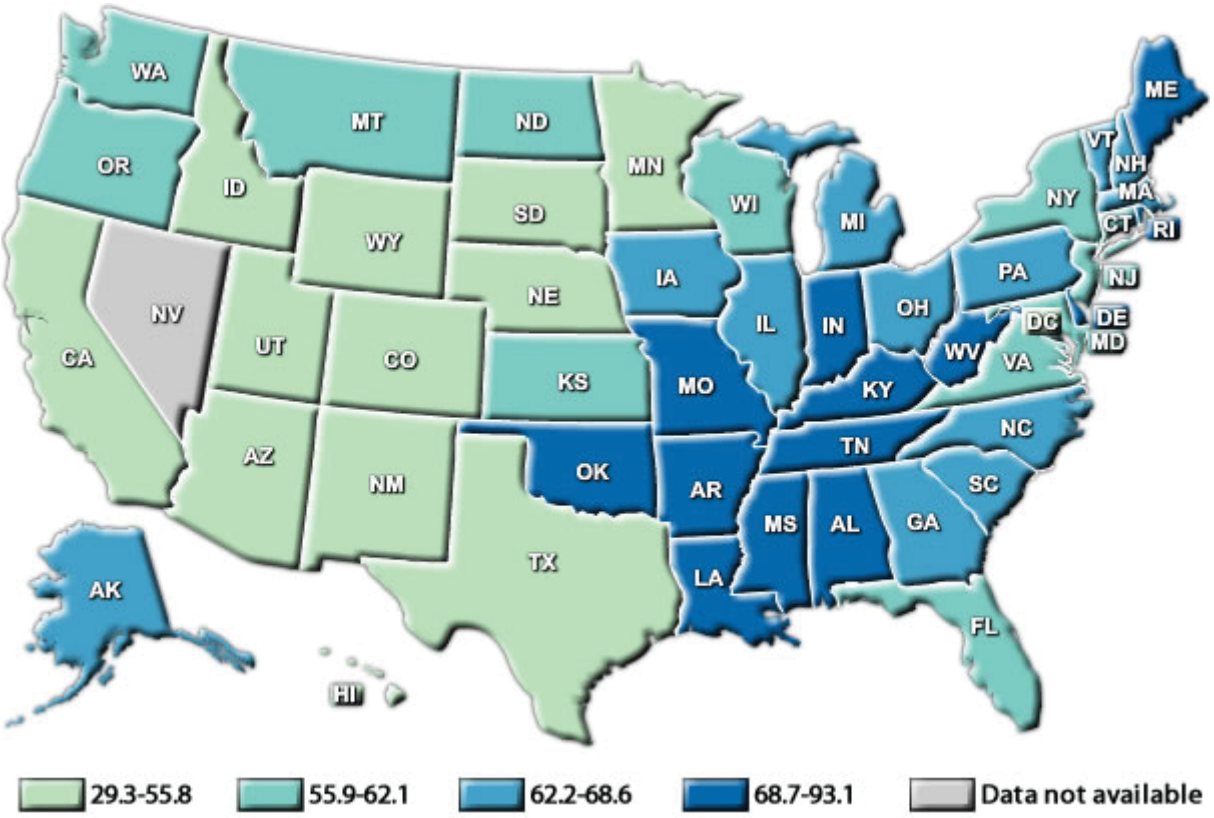


What do the colors mean?

Zone 1 counties have a predicted average indoor radon screening level greater than 4 pCi/L (picocuries per liter) **(red zones)**	**Highest Potential**
Zone 2 counties have a predicted average indoor radon screening level between 2 and 4 pCi/L **(orange zones)**	**Moderate Potential**
Zone 3 counties have a predicted average indoor radon screening level less than 2 pCi/L **(yellow zones)**	**Low Potential**

It is important to note that the lung cancer statistics for these areas do not demonstrate that radon is the cause. Statistics of lung cancer rates are presented in Figure 2 (CDC 2014; http://www.cdc.gov/cancer/lung/statistics/state.htm).

Figure 2. Lung cancer rates in the U.S.



Color on Map	Interval	States
	29.3 to 55.8	Arizona, California, Colorado, District of Columbia, Hawaii, Idaho, Minnesota, Nebraska, New Mexico, South Dakota, Texas, Utah, and Wyoming
	55.9 to 62.1	Connecticut, Florida, Kansas, Maryland, Montana, New Jersey, New York, North Dakota, Oregon, Virginia, Washington, and Wisconsin
	62.2 to 68.6	Alaska, Georgia, Illinois, Iowa, Massachusetts, Michigan, New Hampshire, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, and Vermont
	68.7 to 93.1	Alabama, Arkansas, Delaware, Indiana, Kentucky, Louisiana, Maine, Mississippi, Missouri, Oklahoma, Tennessee, and West Virginia
	Data not available‡	Nevada

*Rates are per 100,000 and are age-adjusted to the 2000 U.S. standard population.
‡Rates are not shown if the state did not meet USCS publication criteria or if the state did not submit

The LNT concept is not supported by the actual impacts to humans; rather, there is a case for the hormesis theory based on actual health impacts. It is important to point out that the confounding factors, such as, smoking and overall air quality, etc., are difficult to segregate from the actual causes of lung cancer, but it is clear that the western states with high radon levels have some of the lowest lung cancer rates.

If the inadvertent intruder analysis radiation exposure level is changed from a maximum of 500 mrem/yr (5 mSv) to 5,000 mrem/yr (50 mSv/yr), then this exposure level becomes closer to the reality of what the general population is now exposed to each year through natural and anthropogenic sources.

Lastly, there is absolutely no need to maintain ALARA since the courts have ruled that ALARA is met at the regulatory limits (i.e., precautionary or ALARA versus causation). Certainly the data collected on exposures to occupational radiation workers demonstrate that the LNT theory is not based on the reality of the actual data collected; that is, 400,000 nuclear power industry workers from 154 facilities in 15 countries had lower than average rates of all cancers, including leukemia. Workers with higher exposure limits than the general population show less incidences of cancer which indicates that the "hormesis" theory is credible.

4. Price-Anderson Nuclear Industries Indemnity Act Considerations

One final consideration for accepting the hormesis theory is to the impact it has on radiation release events from nuclear events. The Price-Anderson Nuclear Industries Indemnity Act (commonly called the Price-Anderson Act) is a United States federal law, first passed in 1957 and since renewed several times, which governs liability-related issues for all non-military nuclear facilities constructed in the United States. Operating commercial facilities have to fund this liability insurance. The U.S. Court system has ruled that the radiation protection standards given in 10 CFR 20 are protective of the general population and to workers (Wiedus and Jose 1996). American Nuclear Insurers (2015) was founded more than 55 years ago to provide insurance to the then emerging U.S. nuclear power industry in order to satisfy the requirements of the federal Price-Anderson Act which established a framework for handling potential liability claims that could arise in the event of a nuclear incident. The insurance pool has over $12 billion collected as of 2011.

Toxic tort cases in the U.S. have resulted in multi-million dollar judgments against industry based on arbitrary risk values ($1*10^{-6}$ to a $1*10^{-4}$) of a single increased cancer. Monsanto paid out around $800 million for the Anniston PCB case and DuPont has lost a verdict in West Virginia for exposure to an intermediary chemical for Teflon for around $500 million. In each of these cases, the plaintiffs' class action pool was limited to around 5,000 to 13,000 individuals. At Fukushima, around 160,000 people have evacuated due to fear of radiation

(http://fukushimaontheglobe.com/the-earthquake-and-the-nuclear-accident/situation-of-the-evacuees). If we take the Monsanto award for 13,000 people for a total of about $800,000, we can come up with a total potential liability for the Fukushima case of $9.85 billion. Thus one accident in the U.S. equivalent to Fukushima could lead to the depletion of the entire insurance pool that has been collected since 1955.

Raising the exposure limit for the general population would have significantly reduced the areas that would have been required to be evacuated at Fukushima and not only saved lives of the 1,600 accidental deaths that occurred during the evacuation, but also left the people in their homes. If we accept the hormesis theory and we reconsider that the courts have ruled that ALARA is the 10 CFR 20 radiation limits for both workers and individuals, then there are significant costs and health benefits that can be realized by adopting "hormesis" and accept a threshold value for radiation versus the LNT concept.

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